UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,448	05/03/2001	Ismat Ullah	TN1A CIP	3068

7590 08/08/2002

Bristol -Myers Squibb Company
Patent Department
P.O. Box 5100
Wallingford, CT 06492-7660

EXAMINER
TRAN, SUSAN T

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/08/2002 6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/848,448	Ullah et al.
Examiner	**Art Unit**
Susan Tran	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 26, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above, claim(s) *32-53* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-31* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of applicant's Petition to Make Special for Patent Application filed 07/25/02, Information Disclosure Statement filed 10/04/01, and Election filed 01/11/02.

Election/Restriction

1. Applicant's election without traverse of Group I (claims 1-31) in Paper No. 6 is acknowledged.

Claims 32-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 6.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper time wise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 5, 7-18, 21-24, 26, 27, and 31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,331,316. Although the conflicting claims are not identical, they are not patentably distinct from each other because, the pharmaceutical composition comprising core and coating of the instant application is obvious over the tablet comprising core and coating of USPN 6,331,316.

Claim Rejections - 35 U.S.C. § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-6, 8, and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Howard et al. US 5,049,394.

Howard teaches high drug load pharmaceutical composition comprising from about 80% to about 96% of drug, *e.g.*, erythromycin; from about 1% to about 12% binder-plasticizer, such as, hydrophilic polymers; 0.5% to about 12% of starch-based excipient, such as, sodium starch glycolate, pregelatinized starch, or polyvinylpyrrolidone; and from about 0.2 to about 5% water-soluble binder, *e.g.*, hydroxypropylmethyl cellulose (columns 2-4). The composition is in spheronizer to form beads that may be coated with film former and plasticizer, and the coated beads can be filled into hard shell capsules (columns 4-5).

5. Claims 1, 2, 4-21, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Morella et al. WO 94/03160.

Morella teaches pelletized composition comprising core including 0.1 to 95% active ingredient, 0.1 to 55% binding agent, filler, carrier, excipients, and glidants (see abstract, and pages 6-7). The active ingredient can be erythromycin (page 4). The core is further being coated with 3 to 50% polymer, 0 to 50% plasticizer (pages 8-9, and formulations 1-7).

Claim Rejections - 35 U.S.C. § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard et al., in view of Morella et al., and Sachs et al. US 6,274,173.

Howard and Morella are relied upon for the reasons stated above. The references are silent as to the teaching of alkaline binder as claimed in claims 23 and 24.

Sachs teaches pharmaceutical composition comprising acid labile active agent, binder, filler, and coating includes plasticizer (columns 3-4). The composition further comprising disintegrants, and lubricants (columns 5-6). Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify the composition of Howard and Morella using carboxymethyl cellulose in view of the teaching of Sachs, because the references teach the advantageous results in the use of binder and disintegrant in pelletize or beads. The expected result would be high dosage acid labile drug in pellet form useful in pharmaceutical art.

7. Claims 3, and 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morella et al., in view of Howard, and Bogardus et al. US 6,207,650.

Howard and Morella are relied upon for the reasons stated above. The references are silent as to the teaching of the specific active agent as claimed in claims 3, and 26.

Bogardus teaches pharmaceutical composition comprising antiviral drug, *e.g.*, 2',3'-dideoxyinosine in the form of powders, granules that can be enteric coated (columns 4-5). Accordingly, it would have been prima facie obvious for one of ordinary skill in the art to prepare the composition of Morella and Howard using 2',3'-dideoxyinosine as active ingredient in view of the teaching of Bogardus because the references teach the advantageous result of acid labile drug in oral dosage form.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Yajima et al., Erkoboni et al., Koszalka et al., and Mitsuya et al. are cited as being of interest for the teaching of acid labile drug.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600